

# BOX MISSING PARTS-REISSUE

Attorney Docket No. 24856

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Group Art Unit: 1633

RECEIVED

REUSER et al.

SFP 2 0 2002

Serial No. 10/046,180

OFFICE OF PETITIONS

Filed: January 16, 2002

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC ANIMALS

## PETITION UNDER 37 C.F.R. § 1.47 FILING WHEN AN INVENTOR REFUSES TO SIGN

Applicants, who have sufficient proprietary interests in the above captioned reissue application, submit this petition to show that a diligent effort was made to secure the Declaration of Frank R. Pieper, who was incorrectly named as an inventor of U.S. Patent 6,118,045 and for which the present reissue application seeks to correct.

#### Statement of Facts:

Upon personal interviews with each of the three inventors who have signed the Reissue Declaration as well as former Pharming employees, applicants through their counsel have discovered the misjoinder. The interviews indicated Dr. Frank R. Pieper had no role in the conception of the instantly claimed invention. Given these inventors relative lack of experience in determining inventorship under U.S. law and in order to be thorough and provide for the possibility that Dr. Pieper may nonetheless have been an inventor without the knowledge of the other three inventors, applicants repeatedly requested evidence of inventorship, e.g. lab notebooks, letters, etc. from Dr. Pieper. No documents were forthcoming.

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Three of Mamed inventors proceeded to sign Reissue Declarations stating that they believe the original patent to be partly inoperative or invalid by reason of misjoinder of inventorship in the original patent. The error relied upon is that Dr. Frank R. Pieper did not invent the subject matter claimed in the original patent. This error arose without any deceptive intention on the part of the applicants.

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Applicants sent the declaration for Dr. Pieper to Ms. Louise M. van den Bos of Erasmus Universiteit. Ms van den Bos, in turn, had two personal meetings with Dr. Pieper, during which he indicated he would not sign the declaration pending the outcome of negotiations between his employer Pharming Group N.V. (Pharming), Erasmus Universiteit, and Genzyme Inc. It is important in this regard that Pharming is a Dutch corporation which filed for receivership protection under Dutch laws, while Genyzme Inc. is a U.S. corporation who had a relationship with Pharming and has announced their intention to acquire Pharming's assets in the press.

Although it is unfortunate that Dr. Pieper has refused to sign the Declaration awaiting the outcome of his financial interests, applicants have an interest in ensuring the validity of their patent and in correcting the misjoinder of a previously asserted inventor.

The last known address of Dr. Pieper is Pharming Group N.V., P.O. Box 451, 2300 AL Leiden, The Netherlands. No signed Declaration has been received from Dr. Pieper.

Applicants who have sufficient proprietary interest in this matter, as shown by the Statement Under 37 CFR 3.73(b) and the accompanying Consents of Assignee, thus file this reissue application to list the correct inventors. Applicants would suffer irreparable damage if said patent is held to be inoperative or invalid and the reissue application correcting the inventorship is not allowed to proceed.

As an additional factor in granting the petition, applicants would like to point out that this technology is currently in clinical trials helping children in at least two locations/hospitals to be treated for Pompe's Disease, a disease which previously had a 100% fatality rate prior to this treatment. Further to this, applicants are in active licensing negotiations with organizations who will be capable of developing a product and bringing it to market. Thus, it is imperative

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that this petition be granted to ensure the validity of a particularly important patent.

#### CONCLUSION

It is respectfully submitted that the requirements under 37 CFR 1.47(a) have been satisfied. Applicants have been unable to obtain a signed declaration by Frank R. Pieper asserting that he is not an inventor. The applicants will suffer irreparable damage if the reissue application is not accepted in the name of the three inventors listed as Arnold J.J. Reuser, Ans T. Van der Ploeg and Martin Ph. Verbeet. Declarations executed by these three inventors are attached.

A check for \$130.00 is attached to this petition as set forth under 37 CRF S 1.17(h).

Any questions regarding this petition should be directed to the undersigned attorneys.

Respectfully submitted,

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